TSRH® Spinal System

510(k) Summary

NOV 21 2008

November 2008

I. **Company:**

Medtronic Sofamor Danek USA
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Melisa Lansky, M.B.A.
Regulatory Affairs Specialist

II. **Proposed Proprietary Trade Name:** TSRH® Spinal System

III. **Classification Name(s):**

Metallic Bone Fixation Appliance
Class: III
Product Code(s): NKB, MNH, MNI, KWP
Regulation No.: 888.3050; 888.3070

IV. **Legally Marketed Devices:** TSRH® Spinal System (K072317 SE 9/18/07) and CD HORIZON® Spinal System (K042025 SE 8/25/04)

V. **Description:**

The TSRH® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, staples, plates, and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain implant components from other Medtronic spinal systems can be used with the TSRH® Spinal System. These components include GDLH® rods, rod/bolt connectors, Variable Angle T-bolts, set screws and locking screws; DYNALOK® PLUS bolts, CD HORIZON® Low Profile MULTI-SPAN® CROSSLINK® Plates, VANTAGE™ Anterior Fixation System screws, as well as CD HORIZON® rods, screws, set screws and locking screws.

The hooks are intended for posterior use only and the staples are for anterior use only. The TSRH-3D® and TSRH-3DX™ connectors, and TSRH-3D® and TSRH-3DX™ screws are intended for posterior use only. All CROSSLINK® Plates are for posterior use and the CROSSLINK® Axial and Offset Plates may be used anteriorly as well.

The TSRH® Spinal System components are fabricated from stainless steel. Alternatively, they may be fabricated from medical grade titanium alloy or medical grade titanium. Never use stainless steel and titanium implant components in the same construct. The TSRH® Spinal System may be sold sterile or non-sterile.

The purpose of this submission is to add TSRH® Anterior L-Plates to the TSRH® Spinal System. Indications for the TSRH® Spinal System will be updated in this submission.

VI. Indications for Use:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the TSRH® Spinal System is indicated for one or more of the following: (1) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) degenerative spondylolisthesis with objective evidence of neurologic impairment, (3) fracture, (4) dislocation, (5) scoliosis, (6) kyphosis, (7) spinal tumor, and/or (8) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the TSRH® Spinal System is indicated for skeletally mature patients: (1) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint: (2) who are receiving fusions using autogenous bone graft only: (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the TSRH® Spinal System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spondylolisthesis, (3) fracture, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) spinal stenosis, (6) pseudarthrosis, (7) tumor resection, and/or (8) unsuccessful previous attempts at spinal fusion.

When used as a unilateral supplemental fixation device in the antero-lateral thoracic/lumbar region, the TSRH® L-Plate and VANTAGE™ screws are intended for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthritis; and/or failed previous fusion.

For anterior use only the TSRH® Spinal System has the additional indication of: spondylolysis.

VII. Substantial Equivalence:

Documentation, including mechanical test results, provided has demonstrated that the TSRH® Anterior L-Plate and VANTAGE™ Screws are substantially equivalent to similar previously cleared devices such as the TSRH® Spinal System (K072317 SE 9/18/07) and CD HORIZON® Spinal System (K042025 SE 8/25/04). The VANTAGE™ Screws were previously cleared in K023797 (SE 12/16/02).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2008

Medtronic, Inc.
% Ms. Melisa Lansky
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, TN 38132

Re: K081080
Trade/Device Name: TSRH® Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP, KWQ
Dated: November 19, 2008
Received: November 20, 2008

Dear Ms. Lansky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081080

510(k) Number (if known):

Device Name: TSRH® Spinal System

Indications for Use

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For anterior use only the TSRH® Spinal System has the additional indication of: spondylolysis.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081080